AMIRA

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B. 510(k) SUMMARY

Amira Medical Premarket Notification for
The AtLast® DMS (Data Management Software)

1. Submitter's Name, Address, Telephone Number, and Contact Person

Amira Medical
4742 Scotts Valley Road
Scotts Valley, CA 95066
Phone: (408) 440 5448
Facsimile: (408) 439-0907

Contact Person: Nina Peled, Ph.D., MBA
Vice President, Scientific Affairs

2. Date Prepared: 2/21/01

3. Name of Device and Name/Address of Sponsor

Trade name: **AtLast ®Data Management Software (DMS)**

Amira Medical
4742 Scotts Valley Road
Scotts Valley, CA 95066

4. Classification Names:

AtLast DMS is considered an unclassified accessory to glucose test systems; glucose test systems are regulated under 21 CFR 862.1345, Class II: 75 CGA.

The device regulation for a "calculator/data processing module for clinical use" (21 CFR 862.2100) exempts such Class I devices from 510(k) requirements. This regulation is not entirely applicable, however, since the exemption only applies to data processors for clinical laboratory use, and not home use or use in clinic settings.

5. Predicate Device

IN TOUCH® Diabetes Management Software (K984527, Lifescan, Inc., Milpitas, CA)

6. Intended Use/Indications

The Amira Medical DMS is an optional data management hardware/software accessory for use with Amira Medical glucose meters such as the ATLast Blood Glucose System. When used with one of the Amira Medical meters, the DMS permits the transfer of data from the glucose meter memory into a computer for enhanced data management capability.

The AtLast Data Management System (DMS) is intended for use in clinical settings to aid healthcare professionals in the review, analysis, and evaluation of historical glucose results to support effective diabetes management. AtLast DMS was developed for exclusive use with the AtLast Blood Glucose System.

The AtLast DMS is not intended to provide medical advice or guidance

7. Device Description

AtLast DMS is designed to provide healthcare providers access to longitudinal data stored in the glucose meter's memory. The data includes glucose measurements and time and date chronology. AtLast DMS consists of a custom interface cable for connection to a personal computer (PC), and software.

8. Principle of Operation (usage)

The Amira Medical meter (e.g., AtLast) is connected to an IBM® compatible PC with Microsoft ®Windows® based operating platform via a custom interface cable. AtLast DMS retrieves the data from the meter's memory and transmits the data to the PC, and processes and presents the data in user friendly formats (i.e., reports and graphs). The reporting and graphing of such information will assist with the monitoring and interpretation of glucose levels.

9. Data Demonstrating Performance

Validation studies were performed that confirm the accurate, safe, and reliable transmission of the data from the AtLast meter to the PC in printable form. The studies ensure that data from the cleared device were not corrupted in transmission, and were displayed with the same accuracy as was displayed in the device.

Conclusion:

The studies demonstrate that AtLast DMS is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 7 2001

Nina Peled, Ph.D., MBA
Amira Medical
Vice President, Scientific Affairs
4742 Scotts Valley Drive
Scotts Valley, CA 95066

Re: 510(k) NUMBER: K010605
Trade/Device Name: Amira Medical Data Management Software
Regulation Number: 862.1345
Regulatory Class: II
Product Code: CGA
Regulation Number: 862.2100
Regulatory Class: Class I
Product Code: JQP
Dated: February 21, 2001
Received: February 28, 2001

Dear Dr. Peled:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K010605

Device Name: Amira Medical Data Management Software

Indications for Use:

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The AtLast DMS is not intended to provide medical advice or guidance

Jean Cooper

Division Sign-Off)
Division of Clinical Laboratory
10(k) Number K010605

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)